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10/692,122

10/23/2003

Joachim B. Kohn

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07/28/2004

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/692,122

Applicant(s)

KOHN ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

APPLICANT'S INVENTION

1. Applicant's invention is directed to a an implant containing a polymer material as set forth in independent claims 1 and 11.

Note: Claims 1-23 are pending.

DOUBLE PATENTING REJECTIONS

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/691,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a radio opaque device having a dihydroxyl monomer. The claims differ in the claims of the instant invention are not limited to a stent, but read on any device. It would have been obvious to a skilled practitioner that a stent is encompassed in the instant invention because of claim 23 is directed to a stent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/796,847. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims read on devices. The claims differ in that the instant invention reads on specific radio-opaque compounds. It would be obvious to a skilled practitioner that 10/796,847 reads on compounds encompassed by the instant invention because the claims of 10/796,847 read on radio opaque compounds having at least one iodide or bromine ring structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/288,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention encompass those of 10/288,076. The claims differ in that the claims of the instant invention may be optionally substituted with bromine or iodine at R9 while 10/288,076 does not allow for any additional substitution on the same position.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 REJECTIONS

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-23: The claims as written are ambiguous because it is unclear what medical device Applicant is claiming. Applicant is respectfully requested to clarify the claims in order that one may readily ascertain what is being claimed.

Claims 2-4: The claims as written are confusing because in independent claim 1 R9 does not allow for hetero and carboxyl groups in the alkyl. In other words, the alkyl is not optionally interpreted with carboxyl or one or more heteroatoms.

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Claims 1-10: The claims as written are ambiguous because of the phrase 'Y1 and Y2 are independently 0, 1, or 2' appearing in independent claim 1. In particular, all the variables cannot be zero because from the preamble of the claim, at least one bromine or iodine must be present in the structure.

Claim 9: Claim 9 depends upon claim 12. The claim should read on a preceding claim.

Claims 11-23: The claims as written are ambiguous because of the phrase 'Y2 is independently 0, 1, or 2' appearing in independent claim 11. In particular, all the variable cannot be zero because from the preamble of the claim, at least one bromine or iodine must be present in the structure.

Claims 11-23: The claims are ambiguous because in independent claim 11 (line 11), it is unclear what is encompassed by Applicant phrase 'derivatives of biologically and pharmaceutically active compounds'.

102 REJECTION

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mark (US Patent No. 4,195,157).

Mark discloses aromatic polycarbonates of Formula I wherein X_m and X_n are independently a halogen atom (column 2, lines 30-49). The invention of Mark encompasses the instant invention when W of Formula I fulfills condition b as set forth in column 2, lines 53-61. Hence, both Mark and Applicant disclose compositions comprising polymers encompassed by Applicant's Formula I as set forth in independent claim 1.

Note: It should be noted that the intended use of the polymer of independent claim 1 has not been given any patentable weight because a recitation of intended utility in the preamble does not impart patentability to a product.


COMMENTS/NOTES

10. It should be noted that no prior art has been cited against claims 11-23. However, Applicant must address and overcome the 112 and double patenting rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a compound of Formula (III) as set forth in independent claim 11.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
Art Unit 1616

July 26, 2004